

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 07 NOV 2000

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 141-124 PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/04636	International filing date (day/month/year) 24 FEBRUARY 2000	Priority date (day/month/year) 26 FEBRUARY 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 9/14, 9/52, 9/58 and US Cl.: 424/497, 489, 490		
Applicant CHEN, CHIH-MING] ANDRX PHARMACEUTICALS, INC		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  31 JULY 2000	Date of completion of this report  18 SEPTEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer <i>Dr. Konata George</i> KONATA GEORGE
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/04636

**I. Basis of the report****1. With regard to the elements of the international application:\***☒ the international application as originally filed☒ the description:

pages 1-8, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

☒ the claims:

pages 9-11, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

☒ the drawings:

pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:

pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☒ The amendments have resulted in the cancellation of:**

☒ the description, pages NONE  
☒ the claims, Nos. NONE  
☒ the drawings, sheets/fig NONE

**5. ☒ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/04636

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement****Novelty (N)**

Claims	<u>1-12</u>	YES
Claims	<u>NONE</u>	NO

**Inventive Step (IS)**

Claims	<u>1-12</u>	YES
Claims	<u>NONE</u>	NO

**Industrial Applicability (IA)**

Claims	<u>1-12</u>	YES
Claims	<u>NONE</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-12 meet the criteria under Pct Articles 33(2) and 33(3) because the prior art of record does not disclose, teach nor fairly suggest the claimed controlled release dosage form of bupropion hydrochloride comprising a first pellet containing bupropion hydrochloride and hydroxypropyl methylcellulose at a weight ratio of 10:1 to 30:1 and a coating which is a mixture of an acrylic resin soluble in acidic media and ethyl cellulose and further comprising a second pellet containing the same ingredients as stated above in the same amounts and proportions, with an additional inner coating comprising a mixture of an acrylic resin which is soluble in an acidic media and a water insoluble polymer and an outer coating which further comprises an enteric coating polymer.

Claims 1-12 meet the criteria under Pct Articles 33(4) having Industrial Applicability because the claimed invention is useful as a controlled release dosage anti-depressant-tablet.

----- NEW CITATIONS -----

none

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**I. BASIS OF REPORT:**

5. (Some) amendments are considered to go beyond the disclosure as filed:

NONE